

## **PUBLIC HEALTH COUNCIL**

Meeting of the Public Health Council held Tuesday, August 23, 2005, 10:00 a.m., at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Chair Paul Cote, Jr, Commissioner of Department of Public Health, Mr. Manthala George, Jr, Ms. Maureen Pompeo, (arrived late at 10:25 a.m.), Mr. Gaylord Thayer, Jr., and Dr. Martin Williams. Council Members Absent was Ms. Phyllis Cudmore, Mr. Albert Sherman, Ms. Janet Slemenda and Dr. Thomas Sterne. Also present was Deputy General Counsel, Attorney Donna Levin.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. In addition, Chair Cote noted that there would be a presentation on meningococcal vaccine by Assistant Commissioner Alfred DeMaria, M.D.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Robert Knorr, Director, Environmental Epidemiology Program, Ms. Suzanne Condon, Associate Commissioner, Center for Environmental Health; Ms. Sally Fogerty, Associate Commissioner, Center for Community Health; Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control; Mr. Paul DiNatale, Manager, Division of Health Care Quality; Ms. Karen Granoff, Director, Office of Patient Protection; Ms. Joan Gorga, Acting Director, Mr. Jere Page, Senior Analyst, and Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program; and Deputy General Counsels: Atty. Kalina Vendetti and Atty. Carol Balulescu.

### **RECORDS OF THE PUBLIC HEALTH COUNCIL MEETING:**

Records of the Public Health Council Meeting of June 28, 2005 were presented to the Council for approval. After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the Records of the Public Health Council Meeting of June 28, 2005 as presented.

### **PERSONNEL ACTION:**

### **REQUEST APPROVAL OF APPOINTMENTS AND REAPPOINTMENTS TO THE MEDICAL STAFF OF LEMUEL SHATTUCK HOSPITAL:**

In a letter dated August 8, 2005, Paul Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of appointments and reappointments to the various medical and allied health staffs of Lemuel Shattuck Hospital. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously) That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, chapter 17, section 6, the following appointments and reappointments to the various medical and allied health staffs of Lemuel Shattuck Hospital be approved:

<b>APPOINTMENTS:</b>	<b>MASS. LICENSE NO.:</b>	<b>STATUS/SPECIALTY:</b>
Anne Marie Chomat, MD	226085	Consultant/Internal Medicine
Mary Sabolsi, MD	202980	Active/IM Infectious Diseases
Linda Maytan, DDS	21230	Consultant/Dentistry
<b>REAPPOINTMENTS:</b>	<b>MASS. LICENSE NO.:</b>	<b>STATUS/SPECIALTY:</b>
Carol Amick, MD	29350	Consultant/Pathology
Nora Laver, MD	158034	Consultant/Pathology
Donald Tracy, MD	75774	Consultant/Radiology
Farhat Homsy, MD	45108	Active/Surgery
Michael Tarnoff, MD	210453	Consultant/Surgery

**STAFF PRESENTATION: “CENTER FOR ENVIRONMENTAL HEALTH – REPORT ON YEAR TWO RESULTS OF A CDC DEMONSTRATION PROJECT ON THE SURVEILLANCE OF PEDIATRIC ASTHMA IN MASSACHUSETTS”, By Robert Knorr, Director, Environmental Epidemiology Program:**

Dr. Robert Knorr, Director, Environmental Epidemiology Program, accompanied by Associate Commissioner Suzanne Condon, Center of Environmental Health, and Associate Commissioner Sally Fogerty, Center for Community Health Services, presented the Asthma Report to the Council. He said in part, “... The school nurses filled out the survey. This is a simple, one-page piece of information. We constantly have been revising it. We are in the second year. This is the second year report that I am showing you. It has changed from the first year. It will change into the third year, again, to make improvements so that the nurses can best provide the information to us in a least imposing manner, and we are collecting just aggregate information. We are not collecting personal identifying information. It was always our goal to collect aggregate information. There is a lot of interest for us to do it otherwise, but there are a lot of legal implications for us, not being able to do that, and at this time, having the aggregate information has been a big help to us. We are not able to get race and ethnicity information. Unfortunately, it is not on this form because schools just don’t have very good information for that, but that is unfortunate because it was of great interest. And definitely, it is a future goal if we can work with schools. We have part of our planning process working with the State Department of Education. They are very cooperative with us on that, and we have had discussions on how we could improve databases on that.”

Dr. Knorr continued, “We have had very good school participation. We do collect information on individual schools buildings that serve grades K-8, all private and all public schools right now. In year one, we did just focus on public schools, though some private schools, on their initiative, did respond to us and, in year one, we also chose to just target those schools that were participating in an essential health services program here at the Department of Public Health. It’s just less than half the schools in the country, and in Massachusetts, public schools, and we had about 70% participation rate on the first year. That was good. Eighty plus participation in districts: If there are ten schools in a district, if eight participated, then that would be part of that 80% participation. In year two, the report that we are releasing today, we have increased participation rate, even though it was the first year that we went out statewide, all public, all private schools K-8. We were very pleased with the 78% participation of 1600 plus schools, surveying about 640,000 children, that we were able to get asthma prevalence information on. Schools are required to provide the data to us under Massachusetts regulations, but they don’t all do that, for many reasons. A lot of it is resource related. Most districts are participating. We have one or two schools in a district that are not able to participate for one reason or another. We don’t have areas of the state that are not participating such as rural or urban areas. For year one, statewide prevalence was 9.2% and this year it was 9.5%. That means 9.5% of the students who are in grades K-8 public and private schools in Massachusetts have a diagnosis of asthma. We specifically do seek students that have a health provider, evidence of a health provider diagnosis, but it is not always in the school record; but, in most cases, it is. By grade, there is a slight increase as the children are older. Some feel that may be just because the asthma is becoming recognized, but we are not really sure of that. And I don’t have the numbers for gender but males have almost eleven percent prevalence and females an 8% prevalence. There is an obvious difference, which is consistent with the scientific literature.”

Dr. Knorr noted that they obtained some local data that shows that it is not just low income communities and minority populations that have the highest risk for asthma. The only major urban areas that made the top of the prevalence lists are Springfield and Holyoke.

In conclusion, Dr. Knorr said in part, “Now, we have more information to really try to understand what is the nature of the disease we are dealing with. There are a lot of things that we are still working on or are going to be working on. We have some important work ahead of us. Part of it to do with linking with some of the census data in order to better characterize what are the communities that have the high rates and the low rates. Also, through environmental public health tracking, we are going to be linking our indoor air quality assessments that are done on a number of schools. We have up to 200 of those and will

look to see if there is an association between school buildings that have an indoor air problem and the rate of asthma...”

Suzanne Condon, Associate Commissioner, Center for Environmental Health, added, “I think the important point here is that the data that has been generated through this effort laid a foundation for us to begin to look more closely at some of those questions and what Bob mentioned about us collecting aggregate data as a way of getting the best handle on asthma surveillance in this state is important because the lack of having to get identifiers makes surveillance much easier but we do actually, through the Department of Education regulations, have access to the student health records if we want to pursue follow-up investigations and, in fact, that’s exactly how we were able to finish the Merrimack Valley Study. We sought permission from the parents, went after the medical records of the children and then did exposure characterization. I think that’s the kind of question that can be answered now that we have the best handle on this in Massachusetts.”

Ms. Sally Fogerty, Associate Commissioner, Center for Community Health, stated in terms of the data, “It is going back and looking at the accuracy of the data and beginning to look at whatever other information or data that might be useful, we could work with school nurses to collect, but also then looking at some of the other data sets we have available, and even though they may not be an absolute linking, look at superimposing what we know around tobacco use in various parts of the state, and overlaying them and what we know around the asthma rates.”

Staff noted that the school nurses have been phenomenal in collecting the data and that they have a strong public health commitment. Staff is really pleased with their participation. Staff is presently analyzing the third year of data and anticipate the patient rate is significantly higher than last years. This second year report is available on the Department’s web site.

#### **No Vote Information Only**

#### **STAFF PRESENTATION: “MENINGOCOCCAL VACCINE”, BY Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control:**

Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control, informed the Council about meningococcal vaccine. He said, “I was asked to brief the Council on sort of an emerging situation with the supply of meningococcal vaccine. Meningococcal is one of the causes of meningitis, inflammation, infection of the membranes that cover the brain and spinal cord. It is second, actually, to the pneumococcus, the pneumonia organism, in terms of causing meningitis, or the bacterial cause of meningitis, but it is still obviously a very important cause of meningitis, and is preventable with vaccine. We have about forty cases of meningococcal meningitis reported each year in Massachusetts. It has actually been down for the past few years, around forty. It was up between 50 and 100 prior to that, despite enhanced surveillance, actually the rate has gone down. It is not entirely clear why that is, but it is certainly welcome. The meningococcus comes in several types. A, B, C, Y and W-135 are the major causes of the disease worldwide. We don’t have very much type A disease. We do have, in particular, B, C, Y and occasional W-135, but most of our disease is due to type B, C, and Y, and that is important because the vaccines that are available protect against A, C, Y and the W-135, and not against the B type of meningococcus, which causes about 25 to 30% of the diseases in Massachusetts and in the United States. The vaccines that are available are two. One vaccine had been available for a number of years, a polysaccharide vaccine, which is very effective, but has a short duration of efficacy, around three to five years, and that is the vaccine, when we were discussing last year the new college requirements, is the vaccine we were discussing. It actually works quite well in that setting because, if students get it just prior to college entry, they are protected for three to five years, which would be their period of exposure. Earlier this year, a new vaccine was licensed, which we have been waiting for – conjugate vaccine, where they take the same polysaccharide from the bacterial and they combined, actually, with diphtheria toxo, the diphtheria vaccine, which boosts the immune response when you give the conjugate vaccine, so you get a much more robust and durable response with the new vaccine. It basically has the same efficacy, but it is more long lasting efficacy. That’s actually now recommended for children entering middle school, as well as children entering high school, and for high risk groups.”

Dr. DeMaria continued, “That’s the good news. The bad news is that both vaccines, which are made by the same manufacturer, are in short supply. There are available but in short supply, below the current demand. There are temporary shortages of both vaccines, in particular the conjugate vaccine, the new one. The national supply is being distributed in a way to maximize the distribution, but the overall amount is below what we need to vaccinate the newly recommended groups. The college students have become an issue right now because last year we promulgated regulations based on a law that was passed last summer, requiring either vaccination against meningococcal disease or a signed waiver declining vaccination before entering college. We have actually been working with the sponsor of that bill, Senator Hart, and others, to revise some of the language in the legislation. Unfortunately, that has not happened. There is a requirement for college entry, all students entering college, to get the vaccine or decline the vaccine. We are hearing from providers and we are hearing from parents that they do not have the access to the vaccine because it is in short supply. Either the older vaccine or the new vaccine would be good to use in this age group, but many people would rather use the new vaccine because of this apparent increased efficacy in terms of duration of response, as well as evidence from other countries where such conjugate vaccine has been available. This actually not only prevents disease but reduces carriage of the bacteria in the upper airway, so it can actually reduce transmission of the disease as well as transmission of the bacteria, as well as the disease itself.”

Dr. DeMaria said further, “There has been a lot of concern about this shortage...The shortage is going to be over in a matter of months. There will be availability of vaccine. We are trying to obtain as much vaccine as we can obtain for the Childhood Vaccine Program, and we are trying to help in any way we can with the acquisition of vaccine for college entry by providers. What we would like to happen is that the vaccine that is available for college students be targeted at those college students at the highest risks, which would be freshmen or other new students entering dormitories because it is in the dormitories that the bacteria get passed around. The same thing happens with military recruits in barracks. Anytime you conjugate the young people together, they exchange their bacteria and, if they have never seen that bacteria before, they are at higher risk of developing invasive disease. So when you look at the risk across all of college students, it is the new college student, living in conjugate living situations that are at highest risk. So, if we get them vaccinated first, at least we are addressing that. For other students, that can’t enter college without vaccine or a decline in vaccine, what we are recommending now is that they decline the vaccine for the time being with the intent of getting the vaccine as soon as it is available. We hope they will note that on their official waiver form developed by the Department, that they are only declining because of availability, that they would like the vaccine when it is available because the colleges can then use that information to do a recall, and they can keep in touch with their provider, or a provider in the area, or the college health service, to get vaccine when it does become available.”

In closing, Dr. DeMaria stated, “The risk overall is about one per hundred thousand. There are approximately 300,000 college students in Massachusetts, we see about two to three cases in college students a year among those forty cases that get reported. All of those cases are not preventable, but a substantial proportion is. The ones that are caused by A, C, Y and W-135 are preventable by vaccination, so we want to encourage the vaccination when the vaccine is available. I think people have to keep the risk in perspective. We want to do everything possible, what we can do to prevent the cases that we can prevent, and provide this vaccine, but it is going to take a few months to do that. In the meantime, we continue to work to address some of the issues related to the logistics of college entry and vaccination. Both with the sponsors of the legislation, as well as the college health services, we are working closely together on this legislation with some proposed amendments. But right now, the national supply is limited and there is not too much we can do about that, except keep awareness alive and make sure that people don’t feel that, by signing this decline at this point, that somehow they are saying they will never get the vaccine, that they can do that to get into college, to get around that barrier, and then receive the vaccine in the near future when it is available.”

A brief discussion followed whereas Dr. DeMaria noted in response to Council Member Thayer that prevention activities with meningitis are basically the same ones we recommend for any droplet-borne disease, including influenza: hand washing, cough etiquette, respiratory hygiene, i.e., not sharing soda cans or cigarettes, etc.

**No Vote/Information Only**

**PROPOSED REGULATION: INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 150.000 (LICENSING OF LONG TERM CARE FACILITIES):**

Attorney Kalina Vendetti, Deputy General Counsel, Department of Public Health, accompanied by Paul DiNatale, Region Manager, Division of Health Care Quality, presented the proposed amendments to regulation 105 CMR 150.000 to the Council. She said in part, "...These amendments will incorporate the requirements of the Executive Office of Health and Human Services (EOHHS) policy entitled "Active Treatment Standard for Specialized Services for Rolland Class Members" into the current regulatory requirements for long-term care facilities."

Staff's memorandum to the Council states that the Loretta Rolland, et al v. Cellucci is a class action law suit filed in 1998 by mentally retarded residents of long-term care facilities. The Amended Complaint alleged that the Defendants failed to provide plaintiff class members with specialized services and community residential supports in a timely manner. The parties entered into a Settlement Agreement in October 1999 under which the Defendants were required to provide all specialized services to all Massachusetts residents with mental retardation or developmental disabilities who currently reside in nursing homes in the Commonwealth who have been determined to need such services.

Attorney Vendetti said further, "In May 2002, the Court ordered the Defendants to provide "active treatment" to class members. Consistent with its coordinating authority, the Executive Office of Health and Human Services (EOHHS) issued through its agencies (the Department of Mental Retardation (DMR), the Department of Public Health ("DPH"), the Division of Medical Assistance, and the Massachusetts Rehabilitation Commission) the policy titled "Active Treatment Standard for Specialized Services for Rolland Class Members". The policy directed DMR to work with nursing facility staff to incorporate specialized service plan strategies into each class member's nursing facility care plan through the development of an integrated DMR service plan called the Rolland Integrated Service Plan ("RISP"). The policy requires that DPH, under its regulatory authority, verify that nursing facilities have incorporated the specialized service plan strategies into the nursing facility care plan ("POC"). To ensure that these requirements are met the Department proposes to amend the regulations to clarify the minimum standards to which all skilled nursing facilities serving Rolland class members in the Commonwealth will be held."

Attorney Vendetti continued, "The main changes the proposed amendments will make in the regulations include adding definitions for carry-over services, developmental disabilities/other related conditions, mental retardation and specialized services; specifically requiring the Pre-Admission Screening and Annual Resident Review for residents with mental retardation, developmental disabilities, or other related conditions ("MR/DD/ORC"); specific requirements for incorporating the RISP and carry-over services into the facility POC; and requirements related to training staff to care for residents with MR/DD/ORC. These amendments will be scheduled for a public hearing in the fall of 2005, and will be brought back to Public Health Council for final approval and adoption by December, 2005."

**NO VOTE/INFORMATION ONLY**

**REGULATION: REQUEST FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 128.000, HEALTH INSURANCE CONSUMER PROTECTION REGULATIONS:**

Ms. Karen Granoff, Director, Office of Patient Protection, presented the amendments to 105 CMR 128.000 to the Council. She said in part, "The proposed changes would add new definitions to the regulation, clarify existing provisions, make changes necessary because of statutory changes, align the regulation with the companion Division of Insurance ("DOI") regulation, and make technical corrections. The Office of Patient Protection (OPP) has responsibility for the oversight of health insurance carriers' internal grievance procedures, certain guarantees of continuity of care and specialty care referral, and the process by which eligible insureds may request an external review of a carrier's adverse determination (a denial of coverage by a carrier based upon a determination that a requested service is not medically necessary). The regulation sets forth requirements in these areas. This regulation has been in effect for

over four years. As a result of OPP's experience dealing with consumers and health plans, and compliance issues that it has identified, OPP proposed amendments to certain sections of 105 CMR 128.000. OPP briefed the Council on these proposed changes on May 24, 2005. OPP held a public comment hearing on the proposed amendments on June 27, 2005. Ten parties submitted comments: Leo Stolbach, M.D. on behalf of the Ad Hoc Committee to Defend Health Care ("Ad Hoc Committee"), AARP of Massachusetts, Blue Cross Blue Shield of Massachusetts, Harvard Pilgrim Health Care, Health Care for All/Health Law Advocates, Massachusetts Association of Behavioral Health Systems, Massachusetts Medical Society, and Susan Fendell on behalf of the Mental Health Coalition (MHC) and Mental Health Legal Advisors." See Staff Memorandum, Exhibited as No.14, 820 for a detailed summary of the comments and testimony.

Staff continued, "Many of the proposed amendments generated no comments or comments that were supportive of the changes, and OPP is recommending that those particular amendments be promulgated as originally proposed. Several parties offered comments that suggested changes to areas of the regulation that were not the subject of the hearing. Those comments will be considered in the future if those areas are being considered for changes."

#### Proposed Changes:

"Actively practicing" and "same or similar specialty:" OPP proposed to define two terms that are used in both the OPP regulation and the companion DOI regulation, 211 CMR 52.00. The terms "actively practicing" and "same or similar specialty" appear in the OPP regulation under two different sections: the requirements for the health plan's internal review of an appeal (see 105 CMR 128.306 (B)), and the requirements for those reviewers who perform an external review of a health plan denial (see 105 CMR 128.410). Thus, the definitions will apply even-handedly to both health plans and the agencies that perform external reviews of health plan decisions. Testimony was divided into two groups: MAHP and HPHC opposed the definitions, while consumer and provider groups supported the addition of the definitions.

#### "Actively Practicing"

MAHP and HPHC argued that "actively practicing" should be defined to permit physicians who have licenses to practice but whose activities are limited to research, teaching, or utilization management (making decisions for insurance carriers) to review appeals for services denied by health plans. They both stated that requiring health plans to refer appeals to outside consultants will increase administrative costs, which will be passed on to consumers. BCBSMA did not comment on this change. Consumer groups strongly supported the proposed definition. HCFA stated that it believed that the intent of chapter 1760 was that reviewers be providers who regularly see patients; "a professional whose practice consists solely of utilization management review, and not treating patients, is not well-equipped to second-guess the appropriateness of an active provider's treatment recommendation." MABHS pointed out that reviewers would have a greater understanding of the practical implications of their decisions if they are also currently treating patients. MMS supported the change and pointed out that in 2002 it adopted a policy that identified research and teaching as non-patient care activities. OPP is proposing that the definition remain as originally proposed. OPP does not consider 'utilization management' to be an active practice, and notes that in chapter 1760, the legislature defines a "clinical peer reviewer" as a provider who holds an unrestricted license and actively practices – thus, legislative intent is quite clear that "actively practicing" is not the same as possessing an active license to practice.

#### "Same/similar specialty"

HPHC and MAHP opposed the change for reasons of administrative costs; HPHC additionally stated that it would diminish the quality of the review process. Both urged OPP to adopt verbatim the definition that appears in NCQA guidelines. (The primary difference between the NCQA definition and OPP's proposal is the addition of the requirement that experience in treating the same condition that is the subject of the dispute shall extend to treatment of children where the age of the patient is relevant to the determination of whether the requested service or supply is medically necessary.) BCBSMA opposed

that addition, but stated that if it is in fact adopted, OPP should require it only where the age of the patient is relevant to the medical necessity determination (which OPP has already included) and that OPP should allow leeway where there may be very few specialists. Consumer groups supported the addition of the pediatric specialty requirement; MABHS noted that this particularly relevant in mental health cases. Two commenters (AARP and MHC) strongly supported the change and urged OPP to add the same requirement for elderly patients. OPP is proposing that the definition remain as originally proposed. OPP does not support the additional requirement of geriatric expertise primarily because chapter 1760 does not apply to Medicare or Medicare supplement policies or Medicare HMOs; thus, any such change would have almost no applicability to the plans regulated by OPP. Additionally, OPP has never seen a case where a medical reviewer treated only younger adults but not elders (as opposed to specialties where a practice may not include children).

#### 105 CMR 128.309: Expedited Review of Grievances

105 CMR 128.309 (1): Currently, the regulation permits a health plan to require an authorization in writing in order for someone other than the patient to appeal a denial of coverage. This requirement ensures that the appeal process is used for the benefit of patients who are being denied care or coverage rather than as a collection vehicle for providers who have payment disputes with insurers. In the case of an appeal on behalf of a current inpatient, however, the appeal is always related to ongoing care of the patient. Additionally, most expedited appeals for continuation of inpatient care involve mental health admissions, where obtaining a patient authorization may be problematic. For this reason, OPP proposed that providers could appeal on behalf of a patient while that patient is confined to a hospital without obtaining written authorization from the patient...OPP is proposing that the requirement remain as originally proposed. OPP regulates disputes between patients and health plans, not where there is a dispute between a patient and a provider. If a provider feels that care is medically necessary, and a health plan has determined otherwise, it is appropriate that a provider be able to assist the patient in advocating for coverage for a service. OPP does not think that this would affect the right of a competent patient to determine his own care.

#### 105 CMR 128.312: Coverage or Treatment Pending Resolution of Internal Grievances

The regulation currently requires health plans to continue ongoing coverage or treatment until an internal appeal is resolved. As written, there is potential for a patient to wait until treatment is ending to file an appeal, thereby automatically ensuring that the health plan's denial is reversed. OPP proposes to close this loophole to provide that health plans must continue coverage only if the appeal was filed on a timely basis...This section addresses the obligation of a health plan to continue coverage of a service that has been denied during the time that an appeal is pending. The original intent of the section was to ensure that a patient would not have to interrupt an ongoing course of treatment while an appeal was pending, but rather could go forward knowing that the health plan would continue to cover the service during the appeal process. The requirement encouraged health plans to act quickly, since if the health plan takes the full 30 business days allowed by law to render a decision, any visits the member has during those 30 business days would have to be covered by the health plan. If the health plan upholds its denial, the member can then decide whether to continue knowing that there will be no coverage, or can file an external review request with OPP."

Staff continued, "When chapter 1760 was enacted, the legislature envisioned that a patient who received a health plan denial would act quickly to challenge the health plan. In fact, however, OPP is now aware of cases where patients or providers have used this section to their benefit, by delaying the filing of the appeal until the course of treatment is nearly complete, thereby ensuring that the health plan will be forced to cover the entire treatment even if the original denial is upheld. For example, under the current regulation, a member who has been approved for 12 physical therapy visits may request an additional 12 visits after completing the initial course of treatment. If the request is denied and the member doesn't file an appeal until after visit 23, the health plan must cover visits 13 through 23 regardless of medical necessity. Under the proposed change, if the patient continued therapy and filed an appeal following visit number 23, the health plan would have to cover visits 13 and beyond only if the appeal finds that the services are medically necessary. If the denial is upheld, the patient is not rewarded for delay. This

change is equitable in that it puts the responsibility on both the member (to file quickly) and on the health plan (to render a timely decision). It is important to note that this proposed change does not in any way affect the right of a patient to file an appeal, nor does it in any way affect the outcome of an appeal. If a patient files an appeal and the decision is made that the service will be covered as medically necessary, then this section is moot – the patient receives coverage for the service in dispute, regardless of the timing of an appeal. It is also important to note that under either version of the regulation, a patient has a right to file an appeal after a course of treatment ends, and the health plan will be obligated to cover the service if upon appeal the service is found to be medically necessary.”

In regards to Continuation of Coverage, Ms. Granoff said, “We had proposed that when an appeal is filed, while someone is receiving services, that there be some sort of time limit placed so that the health plan isn’t at risk for covering the services forever and ever until the person decides to appeal. On one end of the spectrum, the health plans wanted a very short period of time. On the other end, the consumer advocacy group wanted a very lengthy period of time, and we were uncomfortable with drawing any specific line in the sand and, instead, proposed that, during the internal grievance process, coverage would have to continue, provided that the appeal was filed on a timely basis. The Mass. Medical Society recommended that we add that the grievance must be filed on a timely basis, based on the course of treatment, which we thought was a very good addition, and would allow some flexibility to say that the period of time should be longer or not so long, depending on what the patient was being treated for.”

In closing, Ms. Granoff stated, “The last more substantial proposal was to require health plans to acknowledge the external review agency decisions by sending something in writing to the patient and explaining what the next steps are so that they can either get services or get reimbursement for services they already had and that was either largely supported, or we did not receive any comments opposing it.”

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the **Request for Final Promulgation of Amendments to 105 CMR 128.000, Health Insurance Consumer Protection Regulations**; that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14, 820**.

#### **DETERMINATION OF NEED PROGRAM:**

##### **CATEGORY 1 APPLICATION: PROJECT APPLICATION NO. 4-4919 OF BOSTON IVF FOR SUBSTANTIAL CAPITAL EXPENDITURE INVOLVED IN THE RELOCATION, RENOVATION AND REPLACEMENT OF AN AMBULATORY SURGICAL CENTER FROM 40 SECOND AVENUE TO 130 SECOND AVENUE IN WALTHAM:**

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program, presented Project Application No. 4-4919 to the Council. He said, “The applicant is seeking the Council’s approval today for a project improving a substantial capital expenditure associated with relocation of its Waltham practice to a neighboring facility, a provider of comprehensive infertility services at five sites in the Metropolitan Boston area. Boston IVF is subject to DoN regulations by virtue of its on site surgical program and is licensed as an ambulatory surgery center. The Boston IVF Surgery Center provides invitro fertilization services, gynecological surgery and cataract surgery. The latter service was initiated to maintain a service needed by the local elderly population after the closing of Waltham Hospital. Forced to relocate at the expiration of its lease at 40 Second Avenue in Waltham, Boston IVF will move up the street to 130 Second Avenue. The DoN project scope consists of the renovation and **fit-out** of the surgery center portion of the new space, a seven thousand, two hundred eighty-two gross square foot suite, that will accommodate two operating rooms and associated support function. This represents a reduction from its existing eight thousand, five hundred twenty-seven square foot suite, consisting of three operating rooms. The recommended maximum capital expenditure of three million, ninety-four thousand sixty June 2005 dollars will be financed totally with equity. Working with the Office of Healthy Communities, CHNA #18, the applicant has proposed a total contribution of one hundred fifty-four thousand, seven hundred dollars over a five year period to support community health initiatives in the local service area.”

In conclusion, Mr. Plovnick said, "Staff recommends approval of this project with six conditions as enumerated on pages 6 and 7 of the staff summary. The applicant is present this morning and has agreed fully with the staff recommendation."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve **Project Application No. 4-4919 of Boston IVF Inc.**, based on staff findings, with a maximum capital expenditure of \$3,094,060 (June 2005 dollars) and first year incremental operating costs of \$31,961 (June 2005 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14,821**. As approved, this application provides for a substantial capital expenditure involved in the relocation, renovation and replacement of an Ambulatory Surgical Center from 40 Second Avenue to 130 Second Avenue in Waltham. This Determination is subject to the following conditions:

1. The Boston IVF shall accept the maximum capital expenditure of \$3,094,060 (June 2005 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and .752.
2. Boston IVF shall contribute 100% in equity of the final approved maximum capital expenditure.
3. For Massachusetts residents, Boston IVF shall not consider ability to pay or insurance status in selecting or scheduling patients for cataract surgery services.
4. Boston IVF is cognizant of Chapter 111L of the Massachusetts General Laws and will comply fully with said chapter and any regulations and policies developed thereunder.
5. Boston IVF has agreed to provide a total of \$154,700 over 5 years to fund the following community health initiatives:
  - a. \$20,300 per year over five (5) years for a total of \$101,500 will be provided to support programs and projects for disease prevention services and health promotion programs determined by the West Suburban Community Health Network (CHNA 18), in consultation with the Department's Office of Healthy Communities (OHC), to address priority issues. From this allocation, CHNA 18 will distribute \$3,045 per year up to five years to "Healthy Waltham" to support its community driven action plan. CHNA 18 will invite a representative from Boston IVF to sit on any mini-grant process committee or other committee associated with this funding. CHNA 18 and OHC agree that any grant or award of such funds will be to programs that agree to provide information concerning program accountability, including outcomes measurement information, regardless use of the funds. Boston IVF also has agreed to work with OHC and CHNA 18 to determine which organizations will serve as the fiscal recipient (s) for the funds.
  - b. \$4,740 per year over 5 years, a total of \$23,200, will be provided to support programs and projects for Critical Mass, a statewide coalition to eliminate health disparities. Boston IVF will consult with OHC to determine the fiscal agent for this component.
  - c. \$6,000 per year over 5 years, a total of \$30,000, to support the infrastructure of CHNA 18.
  - d. Funding for the initiatives set forth in paragraphs a) and b) above will begin upon notification from Boston IVF to OHC at least 2 weeks prior to the expected date of implementation of the project. Boston IVF also will file all reports as required by the Department. The first payment will be due and payable within 30 days following the actual Project implementation date.

- e. CHNA 18, in consultation with OHC, shall provide to Boston IVF an annual report of the disbursement of funds contributed by Boston IVF, which shall include a summary of the programs to which the funds have been applied, together with outcomes measurement for each program. This report shall be issued no later than 90 days following the end of each 12-month period following the project implementation date. At the request of Boston IVF, CHNA 18 and OHC will meet with representatives of Boston IVF to discuss the annual report.
6. Boston IVF shall have in place the following missing elements of a professional medical interpreter services:
    - Update policies and procedures to prohibit the use of minors as interpreters.
    - Update policies to state that staff cannot ask or encourage untrained people to serve as interpreters.
    - Affirm patients' rights to interpret services at no cost to them and hang the DPH posters at all public entry points to the facility.
    - Develop a reliable and valid system for collection of patient language, race and ethnicity information.
    - Develop a community outreach mechanism to inform community members about the availability of interpreter services at Boston IVF.
    - Translate patient documents and signage into the most commonly spoken languages in the service area as needed.
    - Develop a language needs assessment utilizing internal and external data about LEP needs and encounters.
    - Provide training to staff on effective use of interpreters and telephonic services and relevant policy changes.
    - Follow recommended National Standards for Culturally and Linguistically Appropriate Services ("CLAS") in Health Care found at (<http://www.omhrc.gov/omh/programs/finalreport.pdf>)
    - Further, Boston IVF shall notify the Office of Multicultural Health of any substantial changes to its Interpreter Services Program, submit a plan for improvement addressing the above to OMH within 120 days following DoN approval, and provide Annual Progress Reports to the Office of Multicultural Health on the anniversary date of the DoN approval.

Staff's recommendation was based on the following findings:

1. Boston IVF, Inc. is proposing to renovate space for the relocation of an existing ambulatory surgery center located at 40 Second Avenue, Waltham, MA 02451 to a new location at 120 Second Avenue, Waltham, MA 02451. The relocation is necessary because the lease of the premises at 40 Second Avenue will not be renewable when the current lease term expires.
2. The Department found that the health planning process for this project was satisfactory.
3. The Department found need for the proposed project based upon existing utilization and consistent with the November 15, 1994 Determination of Need Guidelines for Freestanding Ambulatory Surgery Centers.
4. The Department found that the project, with adherence to certain conditions, met the operational objectives factor of the Guidelines.
5. The Department found that the project met the compliance standards of the Guidelines.

6. The Department found the recommended maximum capital expenditure of \$3,094,060 (June 2005 dollars) to be reasonable compared to similar, previously approved projects.
7. The Department found the recommended incremental operating costs of \$31,961 (June 2005 dollars) to be reasonable compared to similar, previously approved projects.
8. The Department found the project, with adherence to certain conditions, to be financially feasible and within the financial capability of the Applicant.
9. The Department found that the project met the relative merit requirements of the Guidelines.
10. The Department found the Applicant's proposed community health initiatives, with adherence to a certain condition, consistent with the Guidelines.

**CATEGORY 1 APPLICATIONS (COMPARABLE):**

**PROJECT APPLICATION NO. 4-3A46 OF TUFTS-NEW ENGLAND MEDICAL CENTER TO PROVIDE POSITRON EMISSION TOMOGRAPHY (PET) SERVICES THROUGH ACQUISITION OF A PET/CT SCANNER TO BE LOCATED IN THE ZISKIND BUILDING:**

**PROJECT APPLICATION NO. 4-3A48 OF BOSTON MEDICAL CENTER TO PROVIDE POSITRON EMISSION TOMOGRAPHY (PET) SERVICES THROUGH ACQUISITION OF A PET/CT BODY SCANNER TO BE LOCATED IN THE CONSOLIDATED CANCER CARE BUILDING:**

**PROJECT APPLICATION NO. 2-4906 OF CENTRAL MASSACHUSETTS MAGNETIC IMAGING CENTER TO PROVIDE POSITRON EMISSION TOMOGRAPHY (PET) SERVICES THROUGH ACQUISITION OF A PET/CT BODY SCANNER TO BE LOCATED ON THE CAMPUS OF UMASS MEMORIAL MEDICAL CENTER:**

Ms. Joan Gorga, Acting Director, Determination of Need Program, made introductory remarks in regards to the three comparable PET applications. She said, "...Staff is pleased to present to you applications from four hospitals, seeking to provide Positron Emission Tomography, or PET services. Staff has been working on PET applications and their reviews are an excellent example of the difficulty of assessing the need for an emerging technology with an evolving reimbursement scheme and rapidly increasing numbers of clinical applications of the technology. When the first PET applications were reviewed in 1994, the technology was used almost exclusively for the neurology, primarily the diagnosis and pre-surgical location of brain disorders, for example, epilepsy. By the time the next applications were reviewed in 1999 and 2002, it was used for the diagnosis and staging of cancer. And now, in 2004 and 2005, its importance in cardiology has been established. Since PET is most frequently an outpatient procedure, data to predict the needs of service has not been readily available. In addition, the federal Medicare Program, which has set the standard for reimbursement for PET, has increased the number of clinical applications, which are reimbursable for PET, from three in 2000 to 23 in 2005. The result is that data for 2000 is not comparable to data for 2002 and for 2004. Previous PET applications were reviewed in 2002, using a methodology involving proxy measures, based on utilization of CT and MRI scans and, as we approached review of these present applications, we had reason to believe that the resulting projections did not match Massachusetts experience."

Ms. Gorga continued, "With the round of PET applications presented to you today, we are pleased to have moved to utilization rates and project data based on the 2004 and 2005 experience of Massachusetts hospitals with DoN approved PET services. With the help of Massachusetts General Hospital and Brigham and Women's Hospital, we have attained data on PET scans organized by the approved clinical procedures, developed rates of procedures per cancer patient and per cardiac patient and applied these rates to the patients at the applicant hospital."

“The four applications for PET services”, stated Ms. Gorga, “which will be presented this morning are New England Medical Center, Boston Medical Center, Central Massachusetts Magnetic Imaging Center and Emerson Hospital. The first three are considered to be comparable applications because each one was reviewed and considered approvable. Staff will present them individually and the Council will vote after all three staff presentations. The fourth application, Emerson Hospital, was originally comparable, but asked in 2004 that its comparability be severed in order not to delay the others during ongoing discussions with staff. Those discussions are complete and Emerson Hospital’s application is being reviewed today at the same meeting as the three comparables.”

Ms. Gorga presented the New England Medical Center application to the Council. She said, “New England Medical Center is a 404 bed tertiary care hospital located in Boston, before you today seeking approval to provide PET scanning through purchase of a PET/CT body scanner to be located in the Division of Nuclear Medicine. The application was reviewed against the factors of the Determination of Need guidelines for PET, which include requirements on oversight training, support services, and the lack of discrimination on the basis of ability to pay. The recommended MCE of the project is \$3,106,509 dollars, which will be funded through an equity contribution and an operating lease from the equipment vendor. The applicant has projected that the scanner will exceed the minimum annual volume of 1,250 scans required in the guidelines. Staff projects that the proposed unit will actually perform over 1600 scans with a combination of cancer, cardiac, research and CT simulation. The applicant offered community initiatives of 155,325 dollars over a five year period for the support of programs through the Boston Alliance and to prioritize community health needs and award funds for projects selected through an open bid community process.”

“In conclusion”, Ms. Gorga said, “Staff recommends approval of the application, Project No. 4-3A46 with the conditions as indicated in staff summary, which have been agreed to by the applicant.”

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the Boston Medical Center and the Central Massachusetts Magnetic Imaging Center projects to the Council. He said, “**Boston Medical Center** proposes to establish the PET service through acquisition of a combination of PET/CT body scanner and associated new construction to accommodate the new unit with the Medical Center’s Consolidated Cancer Care building. The recommended maximum capital expenditure is just over 3.8 million dollars. It will be funded through a 100% equity contribution.” Mr. Page noted that the proposed CT service will exceed the minimum volume requirements. He said, “In this case, it will be just over 1300 projected scans, and also will provide more accessible PET services to the Boston area residents.” Mr. Page further noted that in response to the community initiatives requirement, the Boston Medical Center has agreed to provide a total of \$194,000 over five years to fund projects and programs of the Alliance for Community Health in Boston (Community Health Network Area 19). In addition, they will fund a grassroots effort by the Mattapan Health Care revival, specifically the revival of the community health report card.

Mr. Page stated for the record, a correction to the staff summary: “We had said in the staff summary that Boston Medical Center, through integrated services with the Brigham and Women’s Hospital, provides open heart surgery, thoracic surgery, and some others. However, Boston Medical Center provides these services by itself and not through any shared arrangement with another hospital.”

In closing, Mr. Page said, “staff recommends approval with conditions listed in the staff summary of Project Application No. 4-3A48 of Boston Medical Center Corporation.”

Mr. Page presented the **Central Mass. Magnetic Imaging Center Application**. He said, “Central Mass. Imaging proposes to establish a PET service through acquisition of a PET/CT body scanner and this will be accommodated on the campus of the UMass Memorial Medical Center in Worcester. The recommended MCE is for five million and it will be funded through a package of a 20% equity, a capital lease from the vendor, and a commercial bank loan....The applicant should substantially exceed the minimum volume requirements with about 2400 scans and provide more accessible PET/CT services to Central Massachusetts residents. Central Mass. Imaging has agreed to provide \$198,500 to support prevention efforts targeted towards adolescent mental health services through the HOPE Coalition, consistent with the efforts of the local CHNA, the CHNA #8 in Worcester. In addition, some of the funding will support the development and implementation and other programs of CHNA #8 which are designed to promote civic action and community

conversations to identify health priorities in the Greater Worcester area. In conclusion, we are recommending approval of this project with conditions which are listed in the staff summary.”

A brief discussion followed in which it was noted that the UMass/Shields Mobile unit, a 50/50 partnership will continue to serve the Worcester area as well as this proposed fixed unit.

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve Comparable Applications **Project Application No. 4-3A46 of Tufts-New England Medical Center (a staff summary is attached and made a part of this record as Exhibit No. 14, 822)** to provide Positron Emission tomography (PET) services through acquisition of a PET/CT body scanner to be located in the Ziskind Building; **Project Application No. 4-3A48 of Boston Medical Center (a staff summary is attached and made a part of this record as Exhibit No. 14, 823)** to provide Positron Emission Tomography (PET) services through acquisition of a PET/CT body scanner to be located in the Consolidated Cancer Care Building; and **Project Application No. 2-4906 of Central Massachusetts Magnetic Imaging Center(a staff summary is attached and made a part of this record as Exhibit No. 14, 824)** to provide Positron Emission Tomography (PET) services through acquisition of a PET/CT body scanner to be located on the campus of UMass Memorial Medical Center. These approvals are subject to the following conditions:

**Project Application No. 4-3A46 of Tufts-New England Medical Center**

1. The applicant shall accept the maximum capital expenditure of \$3,106,509 (February 2003 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. NEMC shall contribute 19% in equity (\$601,220 in February 2003 dollars) of the final approved MCE.
3. The applicant shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.
4. With regards to its interpreter service NEMC shall:
  - Develop an annual language needs assessment for the entire health service area as required by 105 CMR 130.1101-130.1108.
  - Maintain current efforts to provide access to competent Interpreter Services to Limited English Proficient clients.
  - Provide annual progress reports to the Office of Multicultural Health (OMH) on the anniversary date of the DoN approval.

A plan to address these interpreter service elements shall be submitted to OMH within 120 days of the DoN approval and NEMC shall notify OMH of any substantial changes to its Interpreter Service program. Also NEMC shall follow National Standards for Culturally and Linguistically Appropriate Services (“CLAS”) in Health Care.

5. The applicant shall provide \$155,325 over a five-year period for support of programs of the Boston Alliance and to prioritize community health needs and award funds in Dorchester. Funding for these initiatives will begin upon implementation and notification to the Department’s Office of Healthy Communities.

The specific service initiatives and associated funding are described below:

**Support for Boston Alliance:** \$3,106 each year for 5 years directly to the Boston Alliance to support ongoing or new projects and programs.

**Health Programs in Dorchester:** \$27,958 each year for 5 years to be awarded through an “open” bid community process for community health needs. NEMC proposes to establish a community health advisory committee to which the three existing CHNA’s in Dorchester would be invited to participate. The advisory committee, comprised of community stakeholders as well as NEMC staff, would work together to categorize and prioritize funding requests and develop selection guidelines and criteria. Proposals submitted to NEMC for funding will be reviewed and recommendations made by an independent review panel made up of community members and professionals who understand the community and the health issues identified in the proposals. Agencies would be required to declare all sources and uses of their existing fundings. Funding will begin upon project implementation and notification to the OHC at least two weeks prior to implementation. NEMC and the CHNA will meet annually to report on all activities, programs and outcomes resulting from the above initiatives and both NEMC and the CHNA will also submit written annual reports to the OHC.

Staff’s recommendation was based on the following findings:

1. NEMC proposes to provide PET services through acquisition of a PET/CT scanner and associated renovation to be located in renovated space in the Division of Nuclear Medicine in the Department of Radiology in the basement of the Ziskind building adjacent to the Radiation Oncology Department.
2. The project meet the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).
3. NEMC has demonstrated demand for the proposed PET/CT scanner as discussed under the Health Care Requirements factor of the staff summary.
4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$3,106, 509 (February 2003 dollars) is reasonable, compared to a similar, previously approved project.
7. The recommended operating costs of \$1, 576,611 (February 2003 dollars) are reasonable compared to a similar previously approved project.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit provisions of the Guidelines.
10. The project, with adherence to a condition, meets the community health service initiatives of the DoN regulations.
11. The Mark Taylor Ten Taxpayer Group registered in connection with the project but did not submit comments.
12. This is one of three comparable applications filed by Tufts-New England Medical Center, (Project No. 4-3A46), Boston Medical Center (Project Number 4-3A48), and Central Massachusetts Magnetic Imaging Center (Project Number 2-4906). Emerson Hospital (Project Number 4-3A49), originally deemed comparable to the above three applicants, requested that its comparability be severed. When considered alone, each of the three remaining comparable applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since the three applications meet the review factors of the PET Guidelines.

**Project Application No. 4-3A48 of Boston Medical Center Corporation:**

1. Boston Medical Center (BMC) shall accept the maximum capital expenditure of \$3,878,590 (February 2003 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. BMC shall contribute 100% in equity (\$3,878,590 in February 2003 dollars) toward the final MCE.
3. BMC shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.
4. BMC has agreed to provide a total of \$194,000 (February 2003 dollars) over five years to fund the following community health service initiatives:
  - \$19,400 per year over five years for a total of \$97,000 will be provided to support projects and programs of the Alliance for Community Health (Community Health Network Area CHNA #19). These projects and programs will be determined in consultation with the Department's Office of Healthy Communities (OHC), based on identified health areas, and will include but not be limited to: support for the Alliance coordinator position, neighborhood mini-grants, training for Alliance neighborhoods, and a city-wide health forum. CHNA #19 and OHC will determine the fiscal agent(s) for these funds.
  - \$19,400 per year over five years for a total of \$97,000 to fund important grass roots efforts by the Mattapan Health Care Revival. Specifically, these funds will be applied towards expenses associated with the Revival's "Community Health Report Card" as well as expenses associated with conducting the Revival's meetings. The next Revival meeting is expected to be held in September 2005.

Funding will begin upon project implementation and notification to the OHC at least two weeks prior to implementation. BMC and the CHNA will meet annually to report on all activities, programs and outcomes resulting from the above initiatives, and both the applicant and the CHNA will also submit written annual reports to the OHC.

Staff finds that with adherence to a certain condition, the project meets the community health initiatives of the DoN Regulations.

5. With regards to its interpreter service, BMC shall:
  - Develop an annual language needs assessment for the entire health service area as required by 105 CMR 130-1101 – through 130.1108.
  - Maintain current efforts to provide access to competent Interpreter Services for Limited English Proficient clients.
  - Provide annual progress reports to the Office of Multicultural Health (OMH) on the anniversary date of the DoN approval.

A plan to address these interpreter service elements shall be submitted to OMH within 120 days of the DoN approval, and BMC shall notify OMH of any substantial change to its Interpreter Services Program. Also, BMC shall follow recommended National Standards for Culturally and Linguistically Appropriate Services ("CLAS") in Health Care.

Staff's recommendation was based on the following findings:

1. BMC proposes to establish a Positron Emission Tomography (PET) service through acquisition of a combination PET/Computerized Axial Tomography (CT) scanner and associated new construction to accommodate the new unit within the Medical Center's Consolidated Cancer Care Building.
2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).
3. BMC has demonstrated demand for the proposed PET/CT service, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$3,878,590 (February 2003 dollars) is reasonable, based on a similar, previously approved project.
7. The recommended incremental operating costs of \$1,799,530 (February 2003 dollars) are reasonable for a PET/CT unit and related hospital construction to accommodate the unit.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit provisions of the Guidelines.
10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.
11. The Mark R. Taylor Ten Taxpayer Group (TTG) registered in connection with the proposed project, but did not submit written comments or request a public hearing.
12. This project is one of three comparable applications filed by Tufts New England Medical Center (Project No. 4-3A46), Central Massachusetts Magnetic Imaging Center (Project No. 2-4906), and Boston Medical Center (Project No. 4-3A48). Emerson Hospital, originally deemed comparable to the above three applicants, requested that its comparability be severed. When considered alone, each of the remaining three applications is capable of being approved, since each has demonstrated demand for PET/CT services. A detailed comparability analysis was not undertaken since these three applications each meet all the review factors of the PET Guidelines.

**Project Application No 2-4906 of Central Massachusetts Magnetic Imaging Center, Inc.:**

1. CMMIC shall accept the maximum capital expenditure of \$5,055,000 (February 2003 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. CMMIC shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.
3. CMMIC shall contribute 20% in equity (\$794,000 in February 2003 dollars) of the final approved MCE.

4. CMMIC shall provide a total of \$198,500 (February 2003 dollars) over five years to fund the following community health service initiatives:
  - \$19,850 per year over five years for a total of \$99,250 will be provided to support prevention efforts targeted towards adolescent mental health services in youth-serving agencies through the HOPE (Healthy Options for Prevention and Education) Coalition, consistent with the efforts of the local Community Health Network Area (“Common Pathways” – CHNA #8), United Way and the Pathways to Progress project. In addition, the HOPE Coalition will submit written annual reports to Common Pathways and the Department’s Office of Healthy Communities (“OHC”) on how the above funds were expended and what outcomes resulted from the programming.
  - \$19,850 per year over five years for a total of \$99,250 will be provided to support the development and implementation of programs and initiatives of Common Pathways (“CHNA #8”). These can include, but are not limited to, developing a set of consensus community indicators and benchmarks for Greater Worcester to promote civic action and convening community conversations on identified health priorities. Common Pathways will select a fiscal agent for these funds, and will also submit written annual reports to OHC on how the funds were expended and what outcomes resulted from the programming.

Funding will begin upon project implementation and notification to the OHC at least two weeks prior to implementation.

5. With regard to its interpreter service, CMMIC shall:

- Develop an annual language needs assessment as required by 105 CMR 130.1101 through 130.1108.
- Assure OMH that all posters stating the availability of interpreter services at no cost are hung in all points of entry at CMMIC, as required by 105 CMR 130.1101 through 130.1108.
- Include CMMIC in the annual progress reports submitted to the OMH on the anniversary date of the DoN approval.
- Develop a plan to reach out to the agencies and natural support groups of new LEP communities in the Worcester area to ensure their members have first-hand information about UMMC interpreter programs and the availability of these services at all sites, including CMMIC.

A plan to address these interpreter service elements shall be submitted to OMH within 120 days of the DoN approval, and CMMIC shall notify OMH of any substantial changes to its Interpreter Services Program. Also, CMMIC shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (“CLAS”) in Health Care.

Staff’s recommendation was based on the following findings:

1. CMMIC proposes to provide Positron Emission Tomography (PET) services through acquisition of a combination PET/Computerized Axial Tomography (CT) scanner, and associated renovation to accommodate the new unit on the campus of UMASS Memorial Medical Center in Worcester.
2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).

3. CMMIC has demonstrated demand for the proposed PET/CT service, as discussed under the Health Care Requirements factor of the staff summary.
4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$5,055,000 (February 2003 dollars) is reasonable.
7. The recommended incremental operating costs of \$2,504,896 (February 2003 dollars) are reasonable for a PET/CT service.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit provisions of the Guidelines.
10. The project, with adherences to a certain condition, meets the community health service initiatives of the DoN Regulations.
11. The Mark R. Taylor Ten Taxpayer Group (TTG) registered in connection with the proposed project, but did not submit written comments or request a public hearing.
12. This project is one of three comparable applications filed by Tufts New England Medical Center (Project No. 4-3A46), Central Massachusetts Magnetic Imaging Center (Project No. 2-4906), and Boston Medical Center (Project No. 4-3A48). Emerson Hospital, originally deemed comparable to the above three applicants, requested that its comparability be severed. When considered alone, each of the remaining three applications is capable of being approved, since each has demonstrated demand for PET/CT services. A detailed comparability analysis was not undertaken since these three applications each meet all the review factors of the PET Guidelines.

**CATEGORY 1 APPLICATION: PROJECT APPLICATION NO. 4-3A49 OF EMERSON HOSPITAL TO PROVIDE POSITRON EMISSION TOMOGRAPHY (PET) SERVICES THROUGH ACQUISITION OF A PET BODY SCANNER TO BE LOCATED IN THE NORTH BUILDING, LEVEL 2 ON THE CAMPUS OF EMERSON HOSPITAL:**

Ms. Joan Gorga, Acting Director, Determination of Need Program, presented Project Application No. 4-3A49 of Emerson Hospital to the Council. Ms. Gorga said, "The applicant, Emerson Hospital, is a 144 bed community hospital located in Concord. The applicant is seeking to provide PET services. The application was reviewed against the factors of the Determination of Need Regulations/Guidelines. The applicant had originally projected that the PET service would exceed the minimum annual volume of 1,250 scans, as required in the guidelines. However, staff projects a much lower utilization, equivalent to about 1/3 of the minimum of 1,250 scans. Emerson offered to construct a docking pad to accommodate a mobile PET unit and to lease the mobile unit for the appropriate two days per week which Staff is recommending as a condition of approval. The applicant is in agreement with Staff recommendation. As with other mobile arrangements recommended by Staff in the past, for both MRI and PET, increases in the numbers of days of service of this unit can be made if the utilization increases and the increase can be documented. The recommended MCE of the Emerson Project is \$727,629, which will be funded through an equity contribution and operating lease from the equipment vendor. Emerson has offered community initiatives of \$21,240 over a three year period for support of programs of the Mass. Partnership for Healthy Communities, and for support of programs and projects for Critical Mass., a statewide coalition to eliminate health disparities."

"In conclusion", stated Ms. Gorga, "Staff recommends approval of the Project Application No. 4-3A49, with conditions as indicated in the Staff Summary. Emerson has agreed to these conditions."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve **Project Application No. 4-3A49 of Emerson Hospital (a summary is attached and made a part of this record as Exhibit No. 14,825)** to provide Positron Emission Tomography (PET) services for two days per week through arrangement with a leased mobile PET unit and the construction of a mobile pad. This Determination is subject to the following conditions:

1. The applicant shall accept the maximum capital expenditure of \$727,629 (February 2003 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. The applicant shall contribute 31% in equity (\$223,629 in February 2003 dollars) of the final approved MCE.
3. The applicant shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.
4. With regards to its interpreter service, Emerson shall:
  - Translate basic patient information documents into the primary languages and make them available to patients with LEP.
  - Develop a structure and timeline to ensure the availability of face-to-face interpreting services in addition to the present telephonic services.
  - Update policies and procedures to reflect the language services available within the system.
  - Provide training to staff on an interpreter policy changes and effective use of interpreters.
  - Develop a reliable and valid system for the collection of language, self-reported race and ethnicity information from patients.
  - Develop a formal plan and provide the necessary systemic support to conduct outreach to non-English speaking communities throughout HSA IV.
  - Translate patient education documents and signage into the most commonly spoken languages in the service area as needed.
  - Submit the Annual Language Needs Assessment utilizing internal and external data. Involve community-based organizations in the Annual Needs Assessment (105 CMR 130.1103).

The Applicant shall submit a plan to address these interpreter service elements to OMH within 120 days of the DoN approval. In addition, the Applicant shall notify OMH of any substantial changes to its Interpreter Services Program, and progress reports shall be submitted annually to OMH on the anniversary date of the DoN approval. Also, the applicant shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (“CLAS”) in Health Care.

5. The Applicant shall provide, before implementation of the project, documentation that the Medical Director has substantial experience in and knowledge of PET.
6. The Applicant shall provide, before implementation of the project, documentation of its certificate of registration and the most recent letter of compliance from the Radiation Control Program of the

Massachusetts Department of Public Health.

7. The Applicant shall provide \$21,240 over 3 years for support of scholarship programs and programs aimed at eliminating health disparities. Funding for these initiatives will begin upon implementation. The specific service initiatives and associated funding are described below.

- **Support for the Mass. Partnership for Healthy Communities:** 50% or \$3,540 each year for 3 years to the Mass. Partnership for Healthy Communities (“Partnership”) in order for the Partnership to award scholarships to eligible community teams or individuals to attend the MassForum.
- **Critical Mass.:** \$3,540 each year for 3 years to support programs and projects for Critical Mass., a statewide coalition to eliminate health disparities.

The applicant will work with the Office of Healthy Communities (“OHC”) to determine the fiscal agent for each component of the funds awarded. The Partnership and Critical Mass. in consultation with the OHC, will provide the applicant an annual report of the disbursement of the funds and will include a summary of the programs to which the funds have been applied.

8. Unless otherwise approved by the Department, Emerson Hospital shall provide PET services only on the days indicated in this approval. Any request for change in number of days served shall be considered a minor change as provided by 105 CMR 100.752.

Staff’s recommendation was based on the following findings:

1. Emerson proposed to provide Positron Emission Tomography (PET) services through acquisition of a PET scanner and associated renovation for location of the scanner in existing space in the Division of Nuclear Medicine.
2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).
3. Emerson has not demonstrated demand for the proposed PET/CT scanner as discussed under the Health Care Requirements factor of the staff summary. Staff, however, has calculated that demand exists for two days of PET service at Emerson and that the service could be provided by a leased, mobile PET unit which staff is recommending as a condition of approval.
4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$727,629 (February 2003 dollars) is reasonable, compared to a similar, previously approved project.
7. The recommended operating costs of \$464,489 (February 2003 dollars) are reasonable compared to a similar, previously approved project.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit provisions of the Guidelines.

- 10.** The project, with adherence to a condition, meets the community health service initiatives of the DoN Regulations.
- 11.** The Mark Taylor Ten Taxpayer Group registered in connection with the project but did not submit comments.

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The meeting adjourned at 11:15 a.m.

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Paul J. Cote, Jr., Chair

LMH/lmh